UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,857	05/23/2001	Claus Sundgreen	55950 (45579)	2048

7590 01/30/2002

Dike, Bronstein, Roberts & Cushman
Intellectual Property Patent Practice
EDWARDS & ANGELL, LLP
130 Water Street
Boston, MA 02109

EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/864,857	Applicant(s) SUNDGREEN ET AL.	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,70,72,74 and 75* is/are rejected.

7)☒ Claim(s) *6-69,71 and 73* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-75 are presented for prosecution on the merits.

Priority

1. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application.

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

Applicant's Information Disclosure Statement received August 27, 2001 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Specification

3. The abstract of the disclosure is objected to because the abstract is not present in a single paragraph. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a **single paragraph** on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Correction is required. See MPEP § 608.01(b).

4. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
© Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(I) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

PLEASE NOTE: A section entitled "A Brief Description of the Drawings" is required.

Claim Objections

5. Claims 6-69, 71, 73 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

6. Claim 2 is objected to because of the following informalities: in claim 2, the phrase "selected from the group consisting of....or" is improper Markush terminology. The phrase should read --selected from the group consisting of....**and**--. Please see MPEP 2173.05(h). Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claims 70, 72, 74, 75 provide for the use of desglymidodrine, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 70, 72, 74, 75 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

For purposes of this office action the claims will be interpreted as method of making pharmaceutical compositions containing desglymidodrine.

8. Claims 4-5, 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 4 recites the limitation "the therapeutically active enantiomeric form of desglymidodrine is (-)-alpha-(aminomethyl)-2,5-dimethoxy-benzenemethanol (-ST 1059)" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

10. Regarding claims 5 and 75, the phrases "such as" and "e.g." render the claim indefinite because it is unclear whether the limitations following the phrases are part of the claimed invention. See MPEP § 2173.05(d).

11. Claim 5 recites the limitation "the therapeutically active enantiomeric form" in line 3. There is insufficient antecedent basis for this limitation in the claim. There is no antecedent basis for this limitation in claim 1.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Luzi et al. AN 1999-13923 (abstract only).

Luzi et al. disclose studying the hypertensive effects of desglymidodrine or ST-1059 in rats. Luzi et al. teach administering pharmaceutical compositions of racemic mixtures of ST-1059 or

the (+) or (-) enantiomeric form of ST-1059. The results show that the (-) enantiomeric form displayed the hypertensive effect. Please see the abstract submitted herewith.

14. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 11139968 ('968) abstract only.

JP '968 discloses antihypertensive transdermal preparations in the form of tapes, wherein the preparations contain the active ingredient 2-amino-1-(2,5-dimethoxyphenyl)ethanol (desglymidodrine). Please see the abstract submitted herewith.

Claims 2-5 are anticipated by JP '968 because the transdermal preparations would inherently contain any one of the claimed enantiomeric forms.

15. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kontani et al. (Abstract only).

Kontani et al. study the effects of alpha1 adrenergic agonists on an experimental urinary incontinence model in anesthetized rabbits by intravenous administration of a composition containing ST-1059 (desglymidodrine). Please see the abstract submitted herewith.

Claims 2-5 are anticipated by Kontani et al. because the composition would inherently contain any one of the claimed enantiomeric forms.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 70, 72, 74, 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luzi et al., supra or JP '968, supra or Kontani et al., supra.

Luzi et al., JP '968 or Kontani et al. as applied above.

Said references do not specifically disclose methods of making the disclosed compositions; however, it would have been obvious to one of ordinary skill in the art to make the pharmaceutical compositions disclosed by Luzi, JP '968 or Kontani using any method which is

well known in the pharmaceutical art. In other words, methods of making pharmaceutical compositions is obvious and well within the capability of the skilled artisan.

Concerning claims 70, 72, 74, 75, which are being examined as a method for preparing a pharmaceutical composition for the treatment of "septic shock" (claim 70); "a condition responsive to alpha1 receptor stimulation" (claim 72); "syncope" (claim 74); and "urinary incontinence" (claim 75) , the Examiner respectfully submits that the ultimate intended use of the pharmaceutical composition is not germane to the issue of patentability of the method of making claim. Please refer to MPEP 2111.02, page 2100-46, where it is stated,

"In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.)".

In the instant case, the Examiner respectfully submits that the intended use of treating the conditions in claims 70, 72, 74 and 75 is of no significance to the process of preparing the pharmaceutical compositions.

Conclusion

Claims 1-5, 70, 72, 74, 75 are rejected.

Claims 6-69, 71, 73 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM
Jan. 27, 2002

Cybille Delacroix-Muirheid
Patent Examiner Group 1600